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SEP 26 2002

Distribution

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM) QUALITY ASSURANCE (QA) TREND EVALUATION FOR THE FIRST SEMESTER 2002

The enclosed report provides the result of the Office of Quality Assurance evaluation of deficiencies trended during the period beginning January 1, 2002, and ending June 30, 2002. This report satisfies the DOE/RW-0333P, Revision 11, *Quality Assurance Requirements and Description* document to provide results of trend evaluations to Affected Organizations.

If you have any questions regarding this subject, please contact either James Blaylock at (702) 794-1420 or me at (702) 794-1460.


Ram B. Murthy, Acting Director
Office of Quality Assurance

OQA:RBM-1609

Enclosure:
OCRWM QA Trend Report for
Quality Program Deficiencies
First Semester 2002

cc w/encl:
File, NQS, Las Vegas, NV
Records Processing Center = "24"

VM 5507
WM 11

Distribution--Memorandum dated

SEP 26 2002

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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE TREND REPORT

FOR

QUALITY PROGRAM DEFICIENCIES

First Semester 2002

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Date 9/19/02

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Date 9/25/02

EXECUTIVE SUMMARY

The purpose of this trend report is to summarize trend-related corrective actions initiated as part of the "real time" analysis conducted during the period January 1, 2002 through June 30, 2002 (first semester 2002). The report also includes a composite analysis of all issues reported during the period and identifies potential emerging quality assurance (QA) program issues, timeliness of corrective actions, and discusses any significant conditions adverse to quality.

There were no significant condition adverse quality trends identified during this report period, however the composite analysis identified two new **emerging** issues relative to the QA program implementation.

- **Untimely submittal of QA Records**

The most significant change in reported deficient conditions is reflected in QA records. Specifically, the major contributor to this program element concerns the submittal of QA records to the Records Processing Center within prescribed time limits. Although it is not unusual to have several deficiencies documented for this condition during a six-month trend period, the conditions documented during this period have doubled (five to ten separate conditions adverse to quality). Since the records have been located and are being submitted, the condition is not considered to be significant at this time. However, failure to initiate a project-wide awareness of records turnover requirements could lead to continued failure to submit required records. The level of increase warrants identification of the concern as an emerging issue at this time that, if not corrected, will lead to a significant condition adverse to quality.

- **Compliance with administratively imposed technical requirements**

Issues associated with the failure to meet administratively imposed technical requirement have increased in terms of inadequate content in implementing documents and failure to follow procedures that implement technical requirements. The evaluation of the QA program element "Procedures" for adequate content and procedure compliance trend codes points to a need to consider this as an emerging issue that needs further management consideration to ensure that procedures are clearly understandable and written with verbatim compliance in mind.

With respect to management of the corrective action program, the time to close deficiencies showed a decrease during this trend period (132 days to 124 days). The introduction of the Quality Observation (QO) process provides a simplified methodology to correct conditions adverse to quality that requires only remedial actions. This process, which has an intended objective to correct conditions within 30 calendar days, currently has an average of nine calendar days to correct and closed the identified conditions. The QOs are not part of the Deficiency Report/Corrective Action Report (DR/CAR) closure time of 124 days.

1.0 Introduction

In accordance with the requirements of the Quality Assurance Requirements and Description (QARD) document, Section 16.2.6, "Quality Trending," trend evaluations are to be performed in a manner and frequency that provide for prompt identification of adverse trends. Each deficiency document is evaluated "real time" for potential adverse quality trends as they are initiated and input to the trend data system. Semi-annual trend reports are prepared in accordance with Administrative Procedure (AP)-16.3Q, *Trend Evaluation and Reporting*, to evaluate the composite performance during the preceding six-month evaluation period. This report provides a summary of trend-related actions taken during the first half of calendar year 2002, i.e., first semester 2002. The report discusses timeliness of corrective actions, summarizes trend-related corrective actions taken during the evaluation period, and identifies potential emerging quality program issues.

2.0 Purpose and Scope

Identification of potential adverse quality trends is an integral part of the corrective action process. As deficiencies are identified, i.e. condition adverse to quality (CAQ) or Nonconformance Reports (NCR), consideration is given as to whether or not the condition exists elsewhere within the implementation of the quality program. As deficiency information is input into the system, the trend program sorts by similar conditions. If a potential adverse quality trend is noted, a trend analysis is conducted.

The scope of this evaluation period is for the first semester 2002, January 1 through June 30, 2002. The trend data includes deficiencies identified on 76 Deficiency Reports (DR), 43 Quality Observations (QO), 7 conditions Corrected During Audits (CDA), and 14 Nonconformance Reports (NCR). No Corrective Action Reports (CAR) were issued during the trend period. The total population of deficiencies that were input to the trend program includes deficiencies identified at supplier facilities (currently 29 of the total 143 trend inputs). Although the majority of the analysis described below concentrates on deficiencies internal to the Office of Civilian Radioactive Waste Management (OCRWM) program, supplier related deficiencies are also discussed.

This report also assesses the Integrated Safety Management (ISM) relative to Suspect Counterfeit items (S/CI).

3.0 Summary

This section summarizes the management of corrective action and trend analysis results for the evaluation period. Adverse trends are identified and described. This section also discusses the emerging issues resulting from analysis and should be of particular interest to management. For purposes of this report and future trend reports, Affected Organization's (AO) management should consider emerging issues as areas of concern which, if left unattended, have the potential to evolve into an adverse quality trend.

The terms used in this report are defined in AP-16.3Q. Two specific terms as used in this report are summarized as follows:

Adverse Quality Trend – Repetitive occurrences of the same problem, or closely related problems, that indicate a deteriorating quality condition or are sufficiently frequent and important to collectively warrant corrective action.

Emerging Issue – A potential adverse quality trend that, after investigation, did not meet the definition for adverse quality trend but requires management attention to prevent further development of a condition requiring formal corrective action.

The evaluation of the 114 internal deficiencies trended during this period considered the relationship of the trend codes assigned to these deficiencies with the previous four semesters (first semester 2000 through second semester 2001). The distribution of deficiencies for the current period and the previous four periods is shown in Table 1 below. The information from this table is used to derive the comparison of deficiencies for the current trend-reporting period with the previous trend reporting periods.

Table 1
Distribution of Deficiencies

| ELEMENT | DESCRIPTION | 2000-1 | 2000-2 | 2001-1 | 2001-2 | 2002-1 |
|---------|-------------------------------------|--------|--------|--------|--------|--------|
| 1 | Organization | 1 | 5 | 1 | | 4 |
| 2 | Program | 11 | 14 | 5 | 17 | 25 |
| 3 | Design | 8 | 9 | 2 | 2 | 2 |
| 4 | Procurement Document Control | 3 | 2 | 2 | 3 | 2 |
| 5 | Implementing Documents | 35 | 15 | 7 | 19 | 25 |
| 6 | Document Control | 2 | 6 | 6 | 7 | 12 |
| 7 | Control of Purchased Items/Services | 6 | 3 | 4 | 3 | 4 |
| 9 | Control of Special Processes | | | | 1 | |
| 10 | Inspection | | | 1 | 1 | |
| 12 | Control of M&TE | 6 | 7 | 10 | 11 | 10 |
| 13 | Handling, Storage, and Shipping | 2 | 1 | 1 | 1 | 2 |
| 15 | Nonconformances | 3 | 2 | 1 | | 2 |
| 16 | Corrective Action | 3 | 6 | 5 | 3 | 3 |
| 17 | QA Records | 32 | 24 | 7 | 7 | 19 |
| 18 | Audits | | 6 | 1 | | |
| 19 | Software | 7 | 4 | 3 | 7 | 7 |
| 20 | Sample Control | 2 | | 5 | 5 | 1 |
| 21 | Scientific Investigation | 9 | 8 | 15 | 17 | 20 |
| 22 | Field Surveying | | | 2 | | |
| 23 | Electronic Management of Data | 5 | 5 | 1 | 3 | 1 |
| 26 | Mined Geologic Disposal System | 3 | | | | |
| 27 | Violation of Technical Requirement | 4 | 1 | | 2 | 4 |

Based on the distribution of deficiencies during the first semester 2002, a chart of AO deficiencies ranked by the number of deficiencies in each program element is shown in Chart 1 below. The chart also compares the number of deficiencies categorized in each area with the distribution reported in the last two trend reports. This chart was derived from the data provided in Table 1 and clearly shows which of the QARD program elements are more affected by quality assurance program deficiencies.

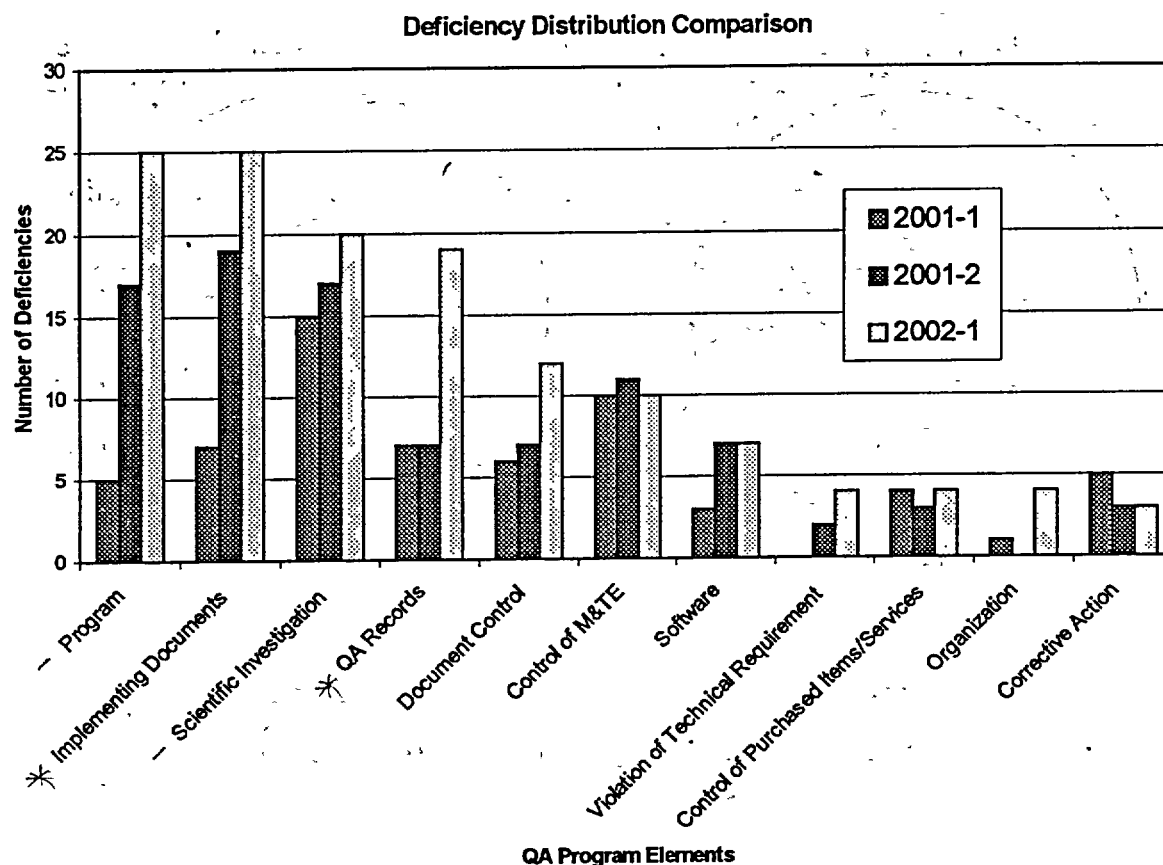
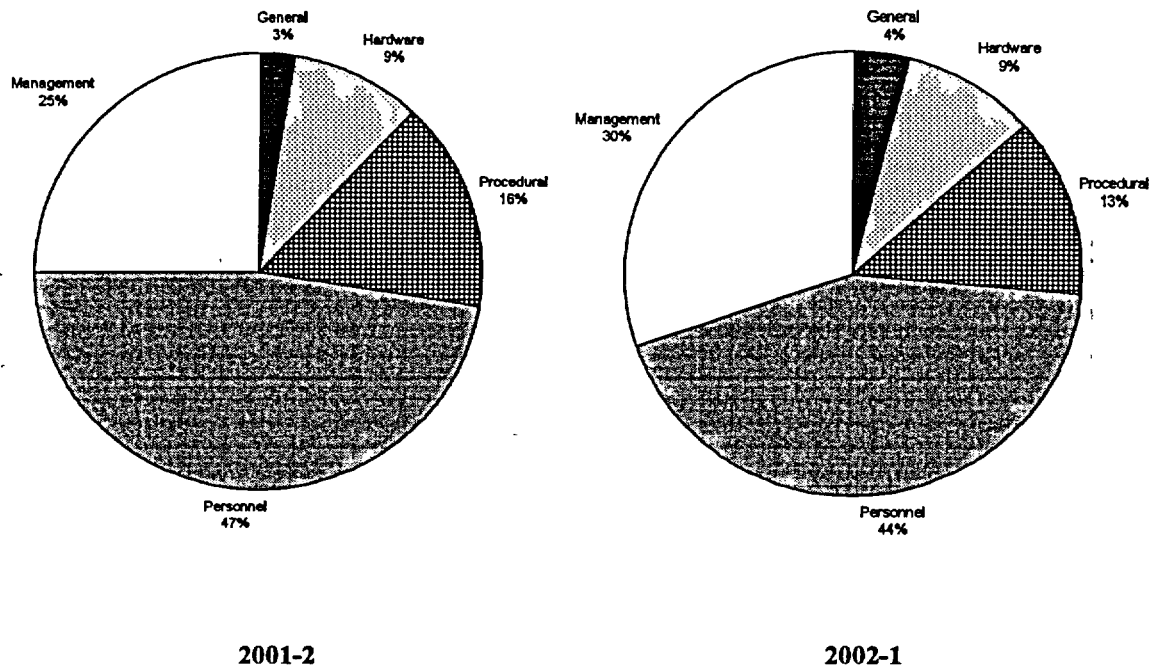


Chart 1

Chart 2 below compares the distribution of causes for the last two semesters by major cause groups. Although these pie charts are presented as a percentage of causes, the change in distribution may provide insight as to the source of problems. The last trend report identified an increase in "inattention to detail," which is one of the major contributors to the personnel errors cause group. Evaluation of the cause data within the personnel error group shows a reduction from about 69% to 52% in the "inattention to detail" cause code. The current trend period therefore shows that the incidences of "inattention to detail" are at the average historical level and no longer considered an emerging trend. Evaluation of the causal codes for other areas does not identify specific areas of concern.



Distribution of Cause Comparison for Last Two Semesters
Chart 2

The format of Chart 3 below was revised beginning with the trend period 2001-1 to show which organizations are reporting conditions adverse to quality. The revision reflects the division of project responsibilities consistent with awarding a new Management and Operating contract to Bechtel SAIC Company, LLC (BSC). Since sources of deficiencies are no longer just "line" or "Office of Quality Assurance (OQA)," the revised format shows the percentage of deficiencies submitted by contributor. "Line" as used in the context of this report refers to all OCRWM, YMSCO, and BSC Organizations other than OQA, BSC QA or concerns personnel. The numbers presented in each column represent the actual number of QOs and DR/CARs initiated by each organization. The line has been listed first (bottom group) to show a direct correlation with the percent of deficiencies initiated and is directly comparable to past trend reports. The size of each of the other participant inputs represents their relative percent contribution. Since the data includes supplier deficiencies, the chart is somewhat misleading in that 19 of the 48 BSC QA deficiencies are related to suppliers. It is also expected that the distribution by organization will change with the increased use of the QO process as an additional means to report and manage some minor conditions adverse to quality. **The chart shows that over the last three trend periods, the percentage reported by the line organization continues to be just below the 30 % level. When combined with BSC's QA group, the BSC contribution continues to be about 70%, including suppliers.**

Deficiency Identification

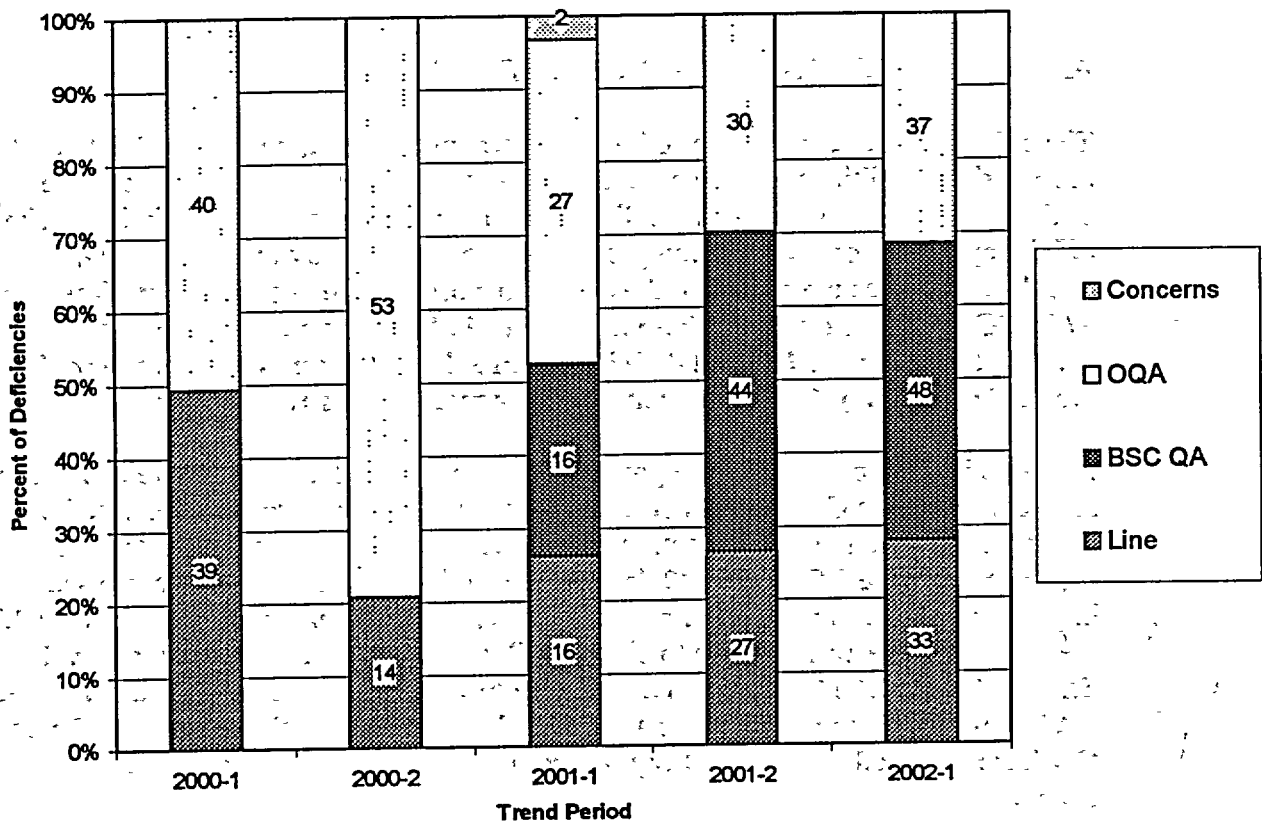


Chart 3

Supplier-related deficiencies were assessed separately from the above. During the trend period, 29 of the trend inputs were related to supplier audits and surveys. This trend program is neither required nor designed to specifically identify adverse trends within individual suppliers; however, a review of this data has the potential to identify OCRWM related procurement issues that manifest themselves as supplier deficiencies. Data relative to supplier deficiencies continues to show several areas that may be related to procurement practices. As such, review of the trend data for supplier related deficiencies (reported last report as an emerging issue) is still considered to be an issue as further described below relative to an existing emerging issue.

The six-month trend period will specifically consider any adverse trends related to S/CI documented through the NCR system. Only one item at the Yucca Mountain Project was identified as suspect/counterfeit for the first six months of calendar year 2002. No S/CI adverse trend is identified during this reporting period.

The management of corrective actions, summary of emerging issues, and summary of adverse trend-related deficiencies issued are described below. A more detailed discussion of the analysis of significant contributors to the number of deficiencies is

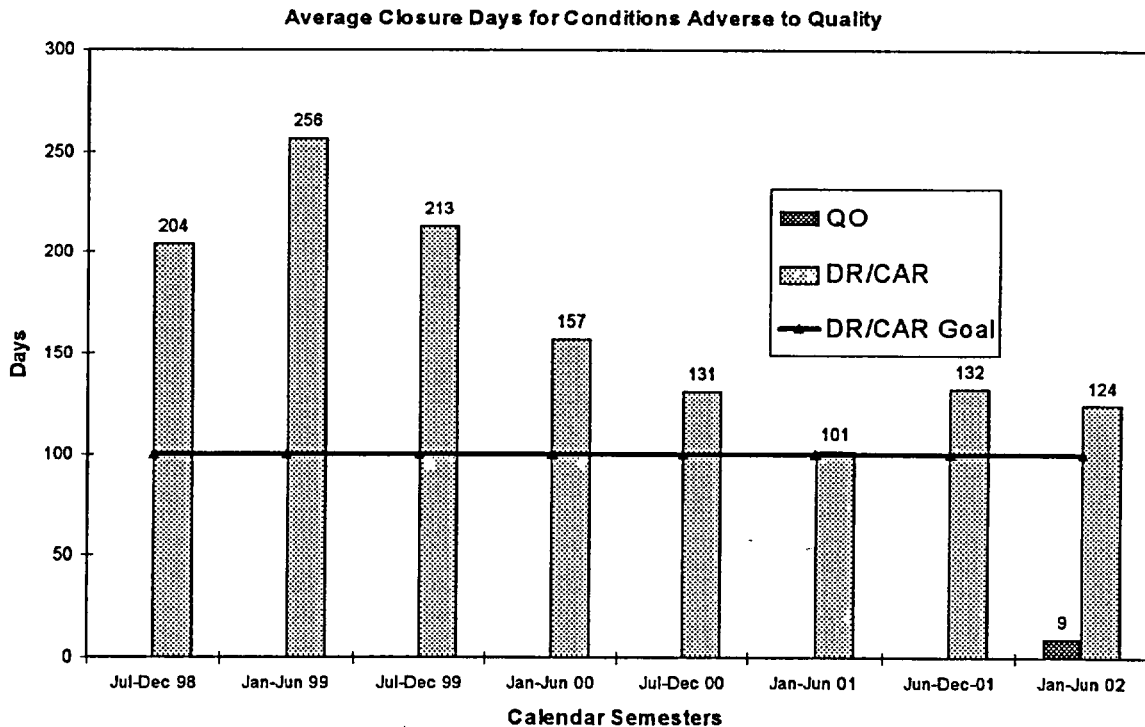
provided further in this report.

A. MANAGEMENT OF CORRECTIVE ACTIONS

The effectiveness of corrective actions is determined, in part, on the trend data evaluation of recurring conditions and the necessity to issue specific CARs as a result of the evaluation. These conclusions are discussed in the subsequent sections below. The efficiency of the corrective action process is also measured by the timeliness of establishing corrective actions and working to closure. **During the evaluation period, 97 DR/CARs were closed with an average of 124 days from issuance to closure. Included within the 97 closed deficiencies are three documents (as compared to six for the last report) that were open a year or more to closure.**

During this trend period, the QO process was implemented as an alternate method to report and manage CAQs. This process manages CAQs that are considered to be isolated in nature and require remedial action only. The process defines an expected life expectancy for the QO of only 30 days before additional management controls are implemented. During this trend period, 43 QOs (since 3/25/02) were issued with 35 of them closed. The average time to close the QOs was nine calendar days from validation. **The addition of the QO process appears to have lowered the threshold for reporting CAQs and significantly improved the timeliness to resolve those issues. The use of a QO has increased the incident reporting in several trend elements as discussed below.**

Chart 4 below shows the average time to close all DR/CARs for the last seven semesters and adds the QO time to close for the current trend period.



B. EMERGING ISSUES

Emerging issues are identified based on quality program issues that may either be developing, or have the potential to develop into a significant CAQ. As such, AO management should strive to reduce recurring incidents of similar issues. This section of the report is intended to review the status of previously identified concerns with the quality program, which were considered to be emerging issues in the last trend report, as well as to identify new emerging issues. Issues that were previously listed and are no longer considered in need of special emphasis have been dropped from this discussion. Emerging issues are as follows:

- **Supplier Deficiencies (Previously reported)**

Review of supplier deficiencies is not intended to identify adverse quality trends within an individual supplier; however, repeat conditions among several suppliers may point to an issue with the procurement process. Supplier deficiencies were the subject of an emerging issue for the last report. Since then, BSC has initiated specific communication actions with suppliers to increase their awareness of the implemented QA program requirements. The trend data relative to supplier deficiencies continues to show issues relative to implementation of supplier quality program elements in need of continued BSC attention. BSC QA continues to discuss these requirements with suppliers and intends to conduct a self-assessment to evaluate the effectiveness of their efforts. However, with the continued identification of similar issues at supplier facilities, the issue is still considered emerging pending and continues to warrant BSC management attention as is being done.

- **Personnel Error and Procedure Implementation (Previously reported)**

The emerging issue identified in the last trend report was based on an increase in "inattention to detail," which is one the major contributors to the personnel error cause group, and increased procedure implementation issues. The introduction of the QO process has documented an increase in procedure implementation issues that are due to minor procedure infractions. Excluding the documented QOs, the evaluation of the cause data within the personnel error group shows a reduction from about 69% to 52% in the "inattention to detail" cause code. The current level of errors due to this cause code is at the average historical level and no longer considered an emerging issue from a trend perspective. However a separate emerging issue related to procedures is noted below. It should be noted that statistics alone does not constitute consideration of an issue as an emerging or adverse trend issue, but rather the significance of the issues are assessed to reach a conclusion on how to report issues.

- **Untimely submittal of QA Records**

The most significant change in reported deficient conditions is reflected in QA records. Specifically, the major contributor to this program element concerns the submittal of QA records to the Records Processing Center within prescribed time limits. Although it is not unusual to have several deficiencies documented for this condition during a six-month trend period, the conditions documented during this period have doubled (five to ten separate conditions adverse to quality). Only two of these conditions were documented on QOs. Since the records have been located and are being submitted, the condition is not considered to be significant at this time. However, failure to initiate a project-wide awareness of records turnover requirements could lead to continued failure to submit required records. The level of increase warrants identification of the concern as an emerging issue at this time that, if not corrected, will lead to a significant CAQ.

- **Compliance with administratively imposed technical requirements**

Issues associated with the failure to meet administratively imposed technical requirement have increased in terms of inadequate content in implementing documents and failure to follow procedures that implement technical requirements. The evaluation of the QA program element "Procedures" for adequate content and procedure compliance trend codes points to a need to consider this as an emerging issue that needs further management consideration to ensure that procedures are clearly understandable and written with verbatim compliance in mind.

C. SUMMARY OF TREND RELATED DEFICIENCIES

The corrective action process allows for "early identification" and documentation of quality programmatic issues that are identified as either repetitive or representative of common issues among AOs. This section is intended to identify those issues for which the trend evaluation identified an adverse quality trend that resulted in a CAR and to provide a status of issued trend CARs. This section also is intended to identify those CARs issued based on timely identification of significant conditions adverse to quality that also appear to be trend related. During this trend period, several of the QA Program elements experienced an increase in condition reporting, however, as noted in discussions below, most of these increases were due to the introduction of the Quality Observation process. As such, it is premature to classify changes as an adverse quality trend until such time as additional data is obtained. Therefore, no CARs for adverse trend were identified during this trend period. The status of the previously issued trend related CAR is as follows:

- **QA Program Requirements related to Training and Qualification of Personnel (Reported last trend period)**

Significant CAQ BSC-02-C-001 was issued during the previous trend period to report that Responsible Managers neither have knowledge of all personnel performing work under their jurisdiction nor have ensured that assigned personnel have completed assigned training. Through a BSC internal surveillance, BSC's initial corrective actions were determined to be incomplete and require additional time to ensure that the entire population of contractor personnel has been completely identified. The

program requires the functional managers to assign position descriptions and training matrices to each subcontract personnel. The subcontract personnel must complete the assigned training prior to implementing quality affecting work per a given program procedure. Resolution of this issue is expected now in mid August.

4.0 Detailed Analysis

Based on the distribution of deficiencies shown on Chart 1, the (QA) Program elements that had five or more deficiencies for the current trend period were evaluated in depth for trend considerations and the results provided in this section. The further breakdown of trend information considered in the analysis is shown in Attachment 1, "Summary Element Code Across Semester", that provides the distribution of specific trend codes for the previous two years. The detailed method of analysis was described in the trend report dated July 7, 1998. The results of these evaluations are as follows:

Program

This number of deficient conditions trended in this category has again shown an increase, i.e. 17 to 25 "hits". However, this category has several distinct work activities under this major element. Evaluation of the specific trend areas as shown for element 2 on Attachment 1 is as follows:

- **Inadequate reviews (management, readiness, peer or document) -** This trend category continues to show a marked increase in trended issues. Evaluation of the deficiency documents that comprised the seven deficiencies for this trend code from the last trend period concluded that the individual issues were not sufficiently related to warrant treatment as a potential adverse trend. Although 16 issues were identified during the current trend period, half of them were documented as relatively insignificant CAQs that required remedial action only (QO). The nature of most of the QOs demonstrates the intent of that process to lower the reporting threshold and, therefore, increasing the number of issues reported. Additional data is needed to establish whether if the level of issue identification represents an adverse quality trend or treatment as an emerging issue. All of the deficiencies taken collectively do not yet warrant such a conclusion. **Although potential issues may be developing regarding the number of incidences in this area, identification of this area as a potential adverse quality trend is considered premature.**
- **Lack of or inadequate training -** Issues related to training and qualification of personnel were documented as a significant CAQ on BSC-02-C-001 and reported in the last trend report. The existing CAR and other training related deficiency documents appear to be adequately managing issues in this area. Only one new training deficiency document (a Quality Observation) was coded in this category. **No new training related concerns have been identified. Existing issues are being adequately managed with current, open DR/CAR documents.**

Implementing Documents

Issues associated with implementing documents are again a significant contributor to deficiencies. The number of "hits" for this trend element has increased from 19 to 25. Specific evaluation of the individual elements and codes as shown on Attachment 1 for element 5 is as follows:

- **Inadequate content in implementing document** – The specific conditions trended in this trend code have increased from 6 to 9 "hits" this trend period. Although several organizations are contributors to this area, evaluation of the specific deficiency documents for this trend period indicates that four of these issues were related to performance activities and resulted in administratively imposed technical requirements not being met. Several of these conditions tie very closely to the issues identified with the trend category of "Failure to follow procedure (technical)" noted below. **Inadequate content procedure appears to be related to an increase in failure to meet administratively imposed technical requirements documented in implementing procedures. This area in conjunction with "Failure to follow procedure (technical)" is considered to be an emerging issue.**
- **Failure to follow procedures (Quality)** – The number of issues have continued to increase in this trend category (9 to 14). However, as with the trend category for "inadequate reviews," the number of deficient conditions trended in this category have been significantly influenced by the lowering of the reporting threshold using the QO process. Since the inception of this process on 3/25/02, six of nine deficiencies were issued as QOs. **As concluded above, potential concerns may be developing regarding the number of incidences in this area, however, identification of this area as a potential adverse quality trend is considered premature until further data concerning the QOs are obtained.**
- **Failure to follow procedures (Technical)** – Five new deficient conditions have been identified in this trend code. . These issues are associated with a failure to comply with an administratively imposed technical requirements documented in implementing procedures. (One DR was issued for missing scheduled meteorological monitoring activities due to the safety stand-down) Two of these issues were also trend coded relative to "Inadequate content in implementing document". **The deficient conditions noted for procedure content along with the issues in this trend category point to an emerging issue that results in not meeting an administratively imposed technical requirement.**

Scientific Investigation

Deficiencies in this trend area are still a significant contributor to the overall conditions adverse to quality. **Although the number of deficient conditions trended in this category has increased, the specific evaluations of the noted deficiencies for the individual trend codes do not indicate the need for additional management attention.** Several of the new additions are related to the QO process and evaluation of the impact of these conditions as a potential adverse trend is still premature.

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Quality Assurance Records

This program element is one of the significant contributors to issues identified during this trend period. Of particular concern is the magnitude of the specific increase in identified issues. Chart 1 shows that the previous trend period reported seven conditions adverse to quality as compared to 19 for this period (nearly triple the previous report). Evaluation of the specific inputs identifies the emerging issue noted below.

- Records were not collected, assembled or transmitted to Records Processing Center – The significant increase in this trend category identifies an issue associated with a failure to submit records within the required procedure time frames. Although it is not unusual to have several deficiencies documented for this condition during a six-month trend period, the conditions documented in this specific code during this period have doubled (five to ten CAQs). **Failure to submit records in a timely manner appears to be a project-wide concern that if continued may lead to the inability to locate critical records needed to support project activities and, therefore, warrants treatment as an emerging issue.**

Document Control

Document control issues have shown an increase in frequency. Evaluation of the individual issues shows that several of the issues were documented using the QO process. **The individual documents that were trended in this area, including the QOs, were reviewed and continues to show no issues at this time that requires additional trend follow-up.**

Control of Measuring and Test Equipment (M&TE)

Deficiencies trended relative to control of M&TE have been about the same for the last three evaluation semesters. Examination of the specific trend codes does not show any adverse quality trend or area of potential concern and shows that issues are distributed through the trend categories. The number of reported incidences relative to M&TE out of calibration has actually decreased from 5 to 2 incidences.

Evaluation of the identified issues does not show that an adverse trend exists in this trend category.

Software

The number of deficiencies trended in this category have not changed from the last trend report. **Evaluation of the individual software deficiencies does not indicate any additional adverse quality trend beyond the conditions already documented on CAR BSC-01-C-002.**

5.0 Conclusions

The number of internal conditions adverse to quality has increased about 30% (88 to 114) this trend period due in part to the introduction of the QO process. The intent of this process, which is to provide a simplified method to report a perceived "minor" condition that requires only remedial action, appears to be having the desired results. QOs have resulted in additional issues trended in several of the criteria that make up the significant contributors to number of conditions. The full impact of this process is still being determined. Except as noted above, it is considered premature to consider the observed increases due to the Quality Observations as an adverse quality trend.

During the trend period, no additional conditions warranted treatment of as an adverse quality trend. However, collective analysis in two areas, i.e. timely submittal of QA records and compliance with technical requirements, points to emerging issues that requires management attention.

With respect to management of the corrective action program, the time to close deficiencies showed a decrease during this trend period (132 days to 124 days). There are currently five deficiencies over a year old that will adversely impact the closure rate when these documents close. With respect to the QO process, over 50 of these documents have been initiated since 3/25/02. During the trend period, 35 were closed with an average time to close of nine days. Initial indicators are that this process will be a significantly more effective process to manage issues that require only remedial action.

Attachment 1

The data listed below represent the distribution of trend coded conditions for each of the major program elements. Each element has been further subdivided into trend code areas to facilitate the analysis for potential adverse trends. This data provides the basis for the detailed discussions above.

| ELEMENT CODE | DESCRIPTION | 2002-1 | 2001-1 | 2000-2 | 2000-1 | 2001-2 | 2002-1 |
|--------------|--|--------|--------|--------|--------|--------|--------|
| 0 | Document was not issued or is not valid | 10 | 1 | 1 | 3 | 1 | 3 |
| 1 | Inadequate organization | 1 | 1 | 1 | 1 | 1 | 1 |
| 1 | No delegation of authority | 1 | 1 | 1 | 1 | 1 | 1 |
| 1 | Organization - Other | 1 | 1 | 1 | 1 | 1 | 1 |
| 2 | Inadequate personnel selection, indoctrination, t | 6 | 3 | 3 | 1 | 1 | 2 |
| 2 | Inadequate program to meet QAFD | 1 | 3 | 5 | 3 | 7 | 16 |
| 2 | Inadequate reviews (management, readiness, peer or | 2 | 1 | 2 | 1 | 3 | 2 |
| 2 | Lack of or inadequate planning | 1 | 3 | 3 | 3 | 3 | 2 |
| 2 | Lack of or inadequate training | 1 | 1 | 1 | 1 | 7 | 1 |
| 2 | Inadequate personnel qualification | 1 | 1 | 1 | 1 | 1 | 1 |
| 2 | QA Program - Other | 1 | 1 | 1 | 1 | 1 | 1 |
| 3 | Control of design input | 1 | 4 | 1 | 1 | 1 | 1 |
| 3 | Inadequate design process/analysis/assumption | 2 | 1 | 1 | 1 | 1 | 1 |
| 3 | Inadequate verification (design reviews, alternate | 1 | 1 | 1 | 1 | 1 | 1 |
| 3 | Inadequate checking | 3 | 3 | 2 | 2 | 2 | 1 |
| 3 | Design error/technical inadequacy | 1 | 1 | 1 | 1 | 1 | 1 |
| 3 | Design control - other | 2 | 3 | 1 | 3 | 2 | 1 |
| 4 | Inadequate requirements in procurement documents | 2 | 2 | 1 | 1 | 2 | 1 |
| 4 | Inadequate procurement document review/approval | 1 | 1 | 1 | 1 | 1 | 1 |
| 4 | Procurement document - other | 1 | 1 | 1 | 1 | 1 | 1 |
| 5 | No procedures or instruction to control and activ | 1 | 3 | 1 | 3 | 1 | 1 |
| 5 | Inadequate content in implementing document | 2 | 3 | 2 | 2 | 6 | 9 |
| 5 | Failure to follow procedure (quality) | 4 | 26 | 5 | 5 | 9 | 14 |
| 5 | Failure to follow procedure (technical) | 5 | 7 | 5 | 5 | 4 | 5 |
| 5 | Procedure can not be implemented as written | 1 | 1 | 1 | 1 | 1 | 1 |
| 5 | Implementing documents - other | 1 | 1 | 1 | 1 | 1 | 1 |
| 6 | Failure to control document | 1 | 1 | 2 | 2 | 1 | 2 |
| 6 | Inadequate distribution and use of documents | 2 | 1 | 2 | 3 | 1 | 1 |
| 6 | Failure to control changes to controlled documents | 1 | 1 | 1 | 1 | 1 | 3 |
| 6 | Use of superseded or outdated documents | 1 | 2 | 2 | 1 | 2 | 3 |
| 6 | Failure to identify an outdated document | 1 | 1 | 1 | 2 | 1 | 1 |
| 6 | Document control - other | 1 | 1 | 1 | 3 | 3 | 2 |
| 7 | Inadequate procurement planning | 1 | 1 | 2 | 1 | 1 | 1 |
| 7 | Inadequate source selection and evaluation | 1 | 2 | 1 | 1 | 1 | 1 |
| 7 | Use of suppliers not on the QSL | 1 | 4 | 1 | 1 | 1 | 1 |
| 7 | Failure to control supplier generated documents | 1 | 1 | 1 | 1 | 1 | 1 |
| 7 | Inadequate acceptance of items or services | 1 | 1 | 1 | 1 | 1 | 1 |
| 7 | Inadequate control of analytical services | 1 | 1 | 1 | 1 | 1 | 1 |
| 7 | Control of purchased items and services - other | 1 | 1 | 1 | 1 | 1 | 1 |
| 9 | Inadequate implementation of special process | 1 | 1 | 1 | 1 | 1 | 1 |

Attachment I (cont)

| Element Code | Description | 2000-1 | 2000-2 | 2001-1 | 2001-2 | 2002-1 |
|--------------|--|--------|--------|--------|--------|--------|
| 10 | 1 Inadequate inspection planning, personnel selection | | | | 1 | |
| 10 | 5 Inadequate documentation of inspection | | | 1 | | |
| 12 | 1 Inadequate control or use of M&TE | 1 | 2 | 2 | 3 | 1 |
| 12 | 3 Inadequate calibration of M&TE | 1 | | 2 | 1 | |
| 12 | 4 Failure to control out of calibration M&TE | 1 | 1 | 1 | | |
| 12 | 5 M&TE out of calibration | 2 | 2 | 4 | 5 | 2 |
| 12 | 6 Inadequate documentation of M&TE calibration | 2 | 2 | | 4 | 2 |
| 12 | 7 Inadequate documentation of use of M&TE | 2 | | | | 1 |
| 12 | 8 No closing calibration | | 2 | 2 | 1 | 3 |
| 12 | 9 Control of M&TE - other | | 2 | 1 | 1 | |
| 13 | 3 Inadequate storage, preservation/maintenance | 2 | | 1 | | 1 |
| 13 | 4 Inadequate marking and labeling | | 1 | | | 1 |
| 13 | 9 Handling, storage, and shipping - other | | | | 1 | 1 |
| 15 | 4 Inadequate disposition and/or disposition approval | | 2 | 1 | | |
| 15 | 9 Nonconformances - other | 3 | | | | 2 |
| 16 | 1 Inadequate identification or classification of con | | 1 | 3 | 2 | |
| 16 | 2 Inadequate follow-up to assure proper implementation | 1 | 1 | 1 | | |
| 16 | 3 Ineffective corrective action | 2 | | 1 | | 1 |
| 16 | 4 Inadequate trending | | 1 | 1 | | 1 |
| 16 | 5 Unlabeled corrective action | | | 1 | 1 | 1 |
| 16 | 9 Corrective action - other | | 3 | | 1 | |
| 17 | 1 Inadequate identification of QA Records | | | | 1 | 3 |
| 17 | 2 Inadequate preparation, completion, or handling of | 26 | 14 | 3 | 1 | 2 |
| 17 | 3 Improper corrections to QA records | 1 | 2 | 1 | | 3 |
| 17 | 4 Records were not collected, assembled or transmitt | 5 | 6 | 4 | 5 | 10 |
| 17 | 6 Inability to retrieve records in a timely manner | | 1 | | | 1 |
| 17 | 8 Inadequate storage of QA Records | | 1 | | | 1 |
| 17 | 9 QA Records - other | | 2 | | 1 | 1 |
| 18 | 1 Inadequate system of comprehensive, planned and do | | 2 | | | |
| 18 | 9 Audits - other | | 4 | 1 | | |
| 19 | 2 Lack of or inadequate controls for acquired softwa | | | | 1 | |
| 19 | 5 Use of unverified/undocumented software | 2 | 1 | | 3 | 2 |
| 19 | 6 Incorrect or incomplete configuration management | 2 | 1 | | 1 | |
| 19 | 7 Inadequate or lacking defect reporting process | | | | | 1 |
| 19 | 8 Software verification or validation inadequate or | 4 | 2 | 2 | 1 | 2 |
| 19 | 9 Software - other | 1 | 1 | 2 | 3 | 2 |
| 19 | 10 Errors or omissions in software qualification doc. | | | | | 1 |
| 20 | 1 Inadequate identification or traceability of sampl | 1 | | 2 | 1 | 1 |
| 20 | 2 Inadequate storage, shipping, or handling of sampl | | | 2 | 3 | |
| 20 | 9 Sample control - other | 1 | | 1 | 3 | 1 |
| 21 | 1 Inadequate or no scientific planning | | | | 1 | |
| 21 | 2 Insufficient traceability (M&TE, method, materials | 1 | 1 | 3 | 3 | 3 |
| 21 | 3 Inadequate information recorded | 2 | 1 | 2 | 3 | 6 |
| 21 | 4 Inadequate or incomplete reports | 3 | 2 | 1 | 2 | |
| 21 | 5 Inadequate performance of scientific investigation | | 1 | | | |
| 21 | 6 Data not identified properly as Q or Non Q | | 1 | 3 | | |
| 21 | 7 Scientific notebook or procedure not used | 1 | | | 4 | 6 |
| 21 | 8 Data review, adequacy, usage | | | | | 3 |
| 21 | 9 Scientific investigation - other | | 1 | | 3 | |

| ELEMENT CODE | DESCRIPTION | 2000-1 | 2000-2 | 2001-1 | 2001-2 | 2002-1 |
|--------------|---|--------|--------|--------|--------|--------|
| 21 | 10 Problem with Scientific notebook | 3 | 1 | 6 | 3 | 7 |
| 21 | 11 Inadequate technical report review | | | | | 1 |
| 21 | 12 Inadequate control of modeling | 1 | 2 | 3 | | |
| 21 | 13 Inadequate control of Data (TDMs or DTN) | | | 3 | 4 | 3 |
| 22 | 1 Field survey controls not established or inadequate | | | 2 | | |
| 23 | 1 Inadequate or incomplete data input/change verify | 3 | 3 | | | |
| 23 | 2 Inadequate or incomplete security access control | | | | | 1 |
| 23 | 9 Electronic management of data - other | 2 | 2 | 1 | 3 | |
| 26 | 9 Mined geologic disposal system - other | 3 | | | | |
| 27 | 2 Specification Violation | 3 | 1 | | 2 | 4 |
| 27 | 9 Other | 1 | | | | |

Attachment I (cont)